

Remarks

Claims 1-43 are presented for the Examiner's review and consideration. In this response, claims 1, 12 and 27 are amended, and claims 42-43 are added. Applicant believes the claim amendments and the accompanying remarks, herein, serve to clarify the present invention and are independent of patentability. No new matter has been added.

35 U.S.C. §102(c) Rejection

Claims 1, 2, 6-7, 11-13, 15-18, 22-28, 30-33 and 37-41 were rejected under 35 U.S.C. §102(c) as being anticipated by MacArthur (6,342,075) ("MacArthur"). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

MacArthur

MacArthur discloses, with reference to Fig. 4 thereof, at least one femoral component 90 and at least one tibial component 100. (Col. 8, lns. 34-36). It can be appreciated that in some situations a patellar component and/or an insert may also form part of the structure, so long as such components are adapted for use with the methods and apparatus of the present invention. (Id). As mentioned previously, the present invention may use both prosthetic components 90 and 100 together or separately to achieve the beneficial effect of total or unicompartmental knee replacement. (Id).

As depicted, femoral component 90 has a generally T-shaped cross-section, as better seen in FIG. 5, and includes a lower surface portion 92 having a substantially spheroidal shape, and a generally planar superior surface 94 with a fixation post or stem 96 extending therefrom. (Col. 8, lns. 44-48).

Stem 96 is adapted to fixably attach to femur 20 and retain femoral component 90 thereto. (Col. 9, lns. 20-22).

After defining the axis of knee 10 and range of motion of knee 10 the surgeon defines the axis of medial condyle 24 of femur 20 and forms an anchoring hole 132, such as by way of a conventional orthoscopic surgical drill 125, as shown in FIG. 8B either alone or in combination with other surgical apparatus such as but not limited to one or more guide wires, jigs, and the like. (Col. 14 ln. 67-Col. 15 ln. 7).

The selected femoral component 90 is inserted and secured within anchoring hole 132 by the use of PMMA, as shown in FIG. 8C. (Col. 15, lns. 22-24). Once femoral component 90 is in place, the surgeon manipulates knee 10 until the location for fixation of additional femoral components 90 is in sight through incision 110. (Col. 15, lns. 44-47). Upon sighting of the next insertion site, the surgeon then follows the above procedure to implant another femoral component 90. (Id).

Once femoral component 90 is inserted, the excess PMMA is removed from the surface of femoral condyle 22 such that no PMMA extends past femoral component 90. (Col. 15, lns. 32-34). Femoral component 90 is inserted to a depth such that lower surface portion 92 of femoral component 90 protrudes from about 2 to about 15 mm above the femoral condyle surface 22. (Id). In an alternative configuration, femoral component 90 protrudes from about 4 to about 10 mm above the femoral condyle surface 22. (Id). In a preferred configuration, femoral component 90 protrudes about 5 to about 8 mm above the surface of femoral condyle surface 22. (Id).

This process is repeated as necessary over as much of the surface of femoral condyle 22 as is necessary, including the intercondylar notch 28. (Col. 15, lns. 50-52). Femoral condyle 22, therefore, may be covered with a plurality of femoral components 90, such as shown in FIGS. 8C, 8D, 9 and 10. (Id).

As such, MacArthur discloses a series of femoral components having a stem and spheroid head, as in a pin. A plurality of such pins is implanted within the condyle to form a bearing surface cooperative with a replacement for the tibial plateau. Each pin is individually glued within a separately drilled hole.

Present Invention

In the present invention, apparatus and procedures are disclosed which may be utilized in association with a revision or partial knee replacement. (§[0290]). With reference to FIG. 40, the present invention includes implants that have interconnectable portions. (§[0673]). Another embodiment of this concept is the combination of limited incision unicompartmental knee replacement with limited incision patellofemoral replacement. (Id). Replacement of the medial or lateral compartment through limited incision surgery and then patellofemoral replacement through the same incision or another incision will lead to faster patient rehabilitation. (§[0674]).

FIG. 91 shows a bicompartiment arrangement that includes trochlear implant 1310 and medial implant 1312. (§[0675]). Implants 1310 and 1312 are dimensioned and configured so that bone 1314 is located between the implants. (Id). FIG. 92 shows an embodiment of a bicompartiment implant 1316 that includes trochlear section 1320 and medial section 1322. (Id). In implant 1316, there is no bone between the sections. (Id). Implant 1316 can be made so that sections 1320 and 1322 are integral. Alternatively, implant 1316 could be modular, being assembled inside the body or outside of the body prior to implantation. (Id).

It is contemplated that rather than enclosing the end portions of the femur and tibia with implants, the implants could be inlaid into the end portion of the femur and/or tibia. (§[0394]). When an implant is to be inlaid into the distal end portion 124 of the femur 126 (FIG. 43), a recess 610 is formed in the distal end portion 124 of the femur 126. (Id).

Once the recess 610 has been formed using the milling cutter 614 in the manner illustrated schematically in FIG. 44, an implant 626 (FIGS. 43 and 45) is positioned in the recess. (§[0396]). The implant 626 fills the recess 610 and has an outer surface 628 (FIG. 45) which forms a continuation of the naturally occurring articular surface 616 formed by the distal end portion 124 of the femur 126. (Id).

The outer surface 628 of the implant 626 may engage an articular surface formed by the boney material of the tibia 214. (§[0397]). Alternatively, the outer surface 628 of the implant 626 may engage the surface of an implant disposed on the tibia 214. (Id).

Thus, the present invention discloses replacing any of the compartments of the knee joint, including replacing the articulating surface with an implant part operative as a weight bearing surface throughout the normal range of motion of the joint (e.g. Fig's. 43, 46, 62, 65, 91, and 92).

Applicant notes that in MacArthur, the femoral pins are described as protruding above the surface of the condyle. Accordingly, pins must be inserted throughout the range of motion of the joint, otherwise a transition from the pins to the condylar surface would be perceived as the joint is used. Accordingly, a plurality of pins is required in MacArthur when replacing the articulating surface.

As such, each of the plurality of pins must be guided or aligned to a correct location and orientation, each pin requiring a precise hole separately drilled into the condyle surface, and each pin must be glued into correct alignment. Maintaining the correct joint angles throughout the range of motion becomes progressively more difficult with each additional implant.

In contrast, in the present invention, replacement of the articulating surface by one implant reduces the time required to properly align the joint, and decreases the difficulty in achieving correct alignment throughout the range of motion. In addition, the time and labor required to install a single implant is significantly less than installing multiple implants. Saving time during surgery is a critically important consideration, at least with respect to the patient's health.

Additionally, MacArthur introduces multiple potential points of failure in a context in which failure of a single part requires revision surgery, with its attendant costs and risks. In particular, each pin in MacArthur must bear all or substantially all of the weight borne by the compartment, and must further bear the angular force, fore and aft, as the joint is moved through its normal motion. Applicant believes that the weight and angular force combined will tend to work the pins loose over time. In contrast, the present invention presents an articulating surface over the entire range of motion, presenting the advantage of a larger, more stable surface, capable of transmitting force along its length, thus being substantially less affected by angular force, and distributing weight along a larger surface area.

In addition, a single articulating surface is more likely to provide a smooth surface than a plurality of separate points, and is further less likely to wear unevenly, or to eventually produce perceptual roughness during movement of the joint.

Claim 1 recites, *inter alia*, a first member including a first elongated articulating surface, the first member affixable to only one of a medial and lateral condyle of a femur portion of the knee joint, the first articulating surface operative as a weight bearing surface throughout the normal range of motion of the joint, for the only one condyle.

Claims 12 and 27 contain similar recitations.

As claims 1, 12 and 27 recite an implant having a member which provides an articulating surface operative as a weight bearing surface throughout the normal range of motion of the joint, and as MacArthur would not function with a single pin, MacArthur does not suggest or disclose, at least, this claim element.

Accordingly, Applicant respectfully submits that claims 1, 12 and 27 are patentable over MacArthur. As claims 2, 6-7 and 11 depend from claim 1, claims 13, 15-18, and 22-26 depend from claim 12, and claims 28, 30-33 and 37-41 depend from claim 27, these dependent claims necessarily include all the elements of their base claims. Accordingly, Applicant respectfully submits that the dependent claims are allowable over MacArthur for the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of the section 102 rejection.

35 U.S.C. §103(a) Rejection

Claims 3-5, 19-21 and 34-36 were rejected under 35 U.S.C. §103(a) as being unpatentable over MacArthur. For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

As described above, Applicant respectfully submits that claims 1, 12 and 27 are patentable over MacArthur. As claims 3-5 depend from claim 1, claims 19-21 depend from claim 12, and claims 34-36 depend from claim 27, these dependent claims necessarily include all the elements

of their base claims. Accordingly, Applicant respectfully submits that the dependent claims are allowable over MacArthur for the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of the section 103 rejection.

Allowable Subject Matter

Applicant acknowledges with appreciation that claims 8-9, 10, 14 and 29 are allowed.

New Claims

Claims 42 and 43 have been added to clarify the invention. Claim 42 recites, *inter alia*, said first member comprises at least two articulating surface portions, connectable in mutual contact within the body to form said first articulating surface.

Thus, claim 42 provides for creating an articulating surface operative as a weight bearing surface throughout the normal range of motion of the joint, where the two surface portions would have the advantage of being more easily passed into the body, while presenting a single articulating surface once connected within the body. This is not disclosed or suggested in MacArthur.

Claim 43 includes the elements of claim 1, and further recites, wherein any of the first, second, and third members may be implanted irrespective of the implantation of any other of the first, second, and third members. No new matter has been added.

Conclusion

In the light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of \$460 is believed to be due for a two month extension. Fees of \$210 for an extra independent claim and \$50 for an extra dependent claim are also believed to be due. These fees are being paid via credit card. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A03-012D).

Respectfully submitted,

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